EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Director-General

Brussels,
GROW.D.4/JFR/az
grow.ddg1.d.4(2018)4046037

By registered letter with acknowledgment of receipt

Mr Simon Bowers
[redacted]

Advance copy by email:
[redacted]

Subject: Your application for access to documents – Ref GestDem No 2018/3587

Dear Mr Bowers,

We refer to your email dated 04/07/2018, in which you made a request for access to documents and which was registered on 04/07/2018 under the above-mentioned reference number.

1. SCOPE OF YOUR REQUEST

You requested access to the National Competent Authority Reports (NCAR) on incidents linked to medical devices, which have been issued by the UK National Competent Authority (MHRA) and registered in the European Databank on Medical Devices (Eudamed) for the last 5 years.

2. DESCRIPTION OF DOCUMENTS IDENTIFIED

We have identified 1029 NCAR reports issued by the UK National Competent Authority between 2014 and 2018 falling under the scope of your request. They are listed in the Annex to this letter.

3. NON-DISCLOSURE OF DOCUMENTS

Having examined the documents requested under the provisions of Regulation (EC) No 1049/2001 regarding public access to documents, I regret to inform you that your request cannot be granted, as disclosure is prevented by exception to the right of access laid down in Article 4 of this Regulation.

All the documents that you seek to obtain, as specified in the Annex to this letter, cover information pertaining to investigations performed by the UK Competent Authority active in the field of medical devices. This authority has the sole responsibility for market control in their territory.

Such information is circulated through Eudamed between the Member States in different phases of the investigations so as to allow all concerned Member States to act as fast as possible on given cases, thus greatly enhancing the effective delivery of public health protection. Member States exchange this information on a confidential basis.

Insofar as the relevant documents concern investigations that are still ongoing, the exceptions laid down in Article 4(2) third indent (*"The institution shall refuse access to a document where disclosure would undermine the purpose of investigations"*) of Regulation (EC) No 1049/2001 apply to the above mentioned documents.

Moreover, some of these requested documents also contain information whose disclosure may undermine the commercial interest of a legal person, as they include industrial information and information covered by intellectual property. Therefore, the exception laid down in Article 4(2) first indent (*"The institution shall refuse access to a document where disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property"*) of Regulation (EC) No 1049/2001 also applies to these documents.

Additionally, we would like to draw your attention to Article 20 of Directive 93/42/EEC concerning medical devices, which provides for the confidential nature of the information exchanged in implementation of that Directive. The documents you have requested access to contain information of the type specified in Article 20(2) that is to be treated as confidential.

The exceptions laid down in Article 4(2) of Regulation 1049/2001 apply unless there is an overriding public interest in disclosure of the documents. We have examined whether there could be an overriding public interest in disclosure, but we have not been able to identify such an interest.

We have considered whether partial access could be granted to the documents that have not been disclosed. However, we have come to the conclusion that the documents are entirely covered by the above exceptions to the right of access to documents.

4. MEANS OF REDRESS

In accordance with Article 7(2) of Regulation 1049/2001, you are entitled to make a confirmatory application requesting the Commission to review this position. Such a confirmatory application should be addressed within 15 working days upon receipt of this letter to the Secretary-General of the Commission at the following address:

European Commission
Secretary-General
Transparency unit SG-B-4
BERL 5/282
B-1049 Bruxelles
or by email to: sg-acc-doc@ec.europa.eu

Yours sincerely,

[redacted]

Annex: documents registers